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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

CHURCH & DWIGHT CO., INC.,

Plaintiff,

v.

SPD SWISS PRECISION DIAGNOSTICS, GMBH,

Defendant.

Civil Action No. 1:14-cv-00585-AJN

SPD SWISS PRECISION DIAGNOSTICS, GmbH'S REPLY MEMORANDUM IN SUPPORT OF MOTION IN LIMINE TO DISMISS ALL FALSE ADVERTISING CLAIMS

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INTRODUCTION

Plaintiff Church & Dwight Co., Inc. ("C&D") opposes SPD Swiss Precision Diagnostics, GmbH's ("SPD") motion *in limine* to dismiss C&D's false advertising claims on two grounds. First, C&D argues that *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228 (2014) "fully disposes" of SPD's motion. But C&D misstates the Supreme Court's holding and ignores its clear statement that, when the U.S. Food & Drug Administration ("FDA") applies its statutory authority to pre-approve labeling, a Lanham Act challenge to the approved claims is barred.

Second, C&D insists that its claim does not conflict with the FDA's exercise of its statutory authority to control the message of SPD's marketing materials. But the record is conclusive that the FDA reviewed, edited, and approved every detail of the challenged packaging, and mandated that FDA-crafted disclosures be made in ***all*** promotional materials for the product, to address precisely the issue C&D claims to be the problem with SPD's advertising. As a matter of law**,** the FDA concluded that its requirements under section 513(i)(E)(1) of the Food, Drug and Cosmetic Act ("FDCA") are sufficient to avoid consumer confusion. Yet C&D urges this Court to conclude that the FDA's labeling requirements were ***not*** adequate to address potential consumer confusion. This is precisely the type of claim – one "undermining an agency judgment" – that the *Pom Wonderful* Court acknowledged is properly barred.

ARGUMENT

I. C&D Has Mischaracterized The *Pom Wonderful* Decision.

A. The Decision In *Pom Wonderful* Turned On Regulations Of General Application Rather Than Preapproval Of A Specific Label.

According to C&D, "*POM Wonderful* holds that the [FDCA] does not preclude Lanham Act false advertising claims **even when FDA permitted or required the challenged advertising.**" C&D's Opp. to SPD's Mot. Lim. ("Opp.") at p. 2 (emph. original). The opinion contains no such a holding. Rather, the Court held that "[c]ompetitors, in their own interest, may

bring Lanham Act claims like POM's that challenge food and beverage labels **that are regulated by the FDCA**." *Pom*, 134 S. Ct. at 2233 (emphasis added). The distinction is crucial.

The Court did address the U.S. Government's argument that the claims should be partially precluded because FDA regulations had "specifically authorized" aspects of the challenged labeling. But the Court did not, as C&D suggests, reject this argument because it does not matter whether the FDA specifically authorized it. Rather, the Court declined to apply this basis for preclusion (1) due to the "practical difficulty" of determining whether regulations of general application have "specifically authorized" a given product label, and (2) because, in that case, the regulation did not create a "ceiling" on what claims might be made.

In contrast, this case does not involve a regulation of general application and therefore presents no "practical difficulty" in determining whether the FDA "specifically authorized" the Product label. The FDA was focused only on the labeling and marketing for ***this*** Product. Similarly, there can be no credible contention that the FDA action was not a "ceiling." Examples of this are everywhere, from the mandate that all promotional materials contain FDA-crafted disclosures on the issue at the center of C&D's claim, to the prohibition on putting more explanatory information on the outside of the box. Indeed, that was the ***purpose*** of this statutory process: for the FDA to control the messaging around the difference between the estimate the Product provides and one based on a woman's last menstrual period ("LMP").

According to C&D, the Supreme Court's rationale applies "if anything, with even more force to FDA's Class II device regulation scheme."[1] This is the case, says C&D, because Class II devices have product inserts and juice products do not. If C&D is suggesting that the FDA's directive to remove certain information from the outside of the box and place it in the insert is

[1] The issue here is not whether the "Class II device regulation scheme" in general precludes C&D's claim. SPD has never made such an argument. The issue is whether the FDA's control, approval and mandatory disclosures for the marketing of ***this Product*** precludes a challenge to the resulting labeling and promotional materials.

not a "ceiling," it entirely misses the point. The FDA clearly intended to and, in fact, did bar further changes affecting the message C&D alleges is false. Dkt. 224 at pp. 20-21; Direct Testimony of Sarah Johnson ("Johnson DT") submitted February 17, 2015 at ¶ 17. The fact that the FDA even dictated what goes on the outside of the box and what goes on the inside ***reinforces*** the conclusion that the FDA action here was indeed a "ceiling." Any ruling requiring more or different disclosures on the outside of the package – whether or not they would help C&D competitively – will collide head-on with FDA mandates.

Two passages in the opinion that C&D failed to address show the failure of C&D's reading of *Pom Wonderful.* First, the Court distinguished the case before it from one in which the FDA "preapproves" a product label. *POM Wonderful*, 134 S. Ct. at 2239. Obviously, this case ***does*** involve an FDA preapproval.[2] Second, the Court distinguished its facts from those in *Geier v. American Honda Motor Co*., 529 U. S. 861 (2000), because "the FDA has not made a policy judgment that is inconsistent with POM's Lanham Act suit." *Pom Wonderful*, 134 S. Ct. at 2241. The opposite is true here: the FDA has made a policy judgment that the limitations it imposed are sufficient to avoid the risk C&D is alleging.

C&D essentially ignored these passages. C&D relegates the Court's preapproval distinction to a footnote, feigning confusion about its significance and dismissing it as a "passing mention." C&D Opp. at p. 17, fn. 7. C&D is entirely silent on the Court's discussion of *Geier*. These omissions speak volumes about C&D's suggested reading of *Pom Wonderful.* [3]

[2] C&D asserts that the approval process for a new drug is "more rigorous" than a Class II medical device clearance process. First, this was not an ordinary Class II clearance process, but the more rigorous "SE with Limitations" review. Second, the record shows that the FDA was heavily focused not only on the challenged advertising, but on C&D's actual allegations. Regardless of level of "rigor," the FDA clearly made a considered judgment pursuant to specific authority in the FDCA and hence warrants preclusive effect.

[3] C&D asserts that it previously "noted a few factual scenarios **not present in this case** as to which preclusion might still apply even after the Supreme Court decided *Pom Wonderful.*" Opp. at p. 18 (emphasis in original). C&D then cites to specific pages in earlier briefs. *Id*. Notably, the cited passages reference *American Home Products Corp. v. Johnson & Johnson*, 672 F. Supp. 135 (S.D.N.Y. 1987) and *Cytyc Corp. v. Neuromedical Systems, Inc.*, 12 F. Supp.

B. C&D Mischaracterizes The Decisions Applying *Pom Wonderful*.

C&D also mischaracterizes the two cases addressing the effect of *Pom Wonderful* on FDCA preclusion. In *JHP Pharm., LLC v. Hospira, Inc.*, No. CV 13-07460 DDP, 2014 WL 4988016 (C.D. Cal. Oct. 7, 2014), a drug manufacturer ("Par") sued a competitor ("JHP") on several false advertising theories. In applying *Pom Wonderful* to JHP's motion to dismiss, the *JHP* court recognized that the Supreme Court's reference to FDA decisions preapproving drug labels "suggests that, at a minimum, the Court might find a Lanham Act claim precluded by the FDCA where it turns on the content of a drug label, especially if that drug label were pre-approved by the FDA." *Id.* at *3. It further observed that the Court's discussion of *Geier* suggests "that a Lanham action might be barred where . . . the Plaintiff's grounds for the Lanham Act claim otherwise conflict with an affirmative policy judgment by the FDA." *Id*. at *4.

C&D ignored this discussion, skipping to the *JHP* court's rejection of an argument ***that SPD does not make***: namely, that *Pom Wonderful* should be limited to food & beverage labeling cases. *JHP Pharm.*, 2014 WL 4988016, at **4-5. SPD's position is that *Pom Wonderful* is distinguishable for precisely the reasons recognized in *JHP*: the Supreme Court carved out of its analysis FDA preapprovals and any other circumstance "where the Plaintiff's grounds for the Lanham Act claim otherwise conflict with an affirmative policy judgment by the FDA."

The *JHP* court's disposition of the motion supports SPD's position. The court denied preclusion of Par's theory that JHP misrepresented that the FDA approved its drug, because it was not disputed that the drug was unapproved, and it was unnecessary to evaluate whether such an approval would be granted. *Id*. at *7. With respect to Par's theory that the JHP drug was not safe and effective, the court said it "might well . . . be precluded entirely," but it did not reach the issue because the substantive allegations were deficient. As to a third theory, that defendant was

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2d 296 (S.D.N.Y. 1998), two of the decisions SPD emphasized in its opening brief as controlling here. In other words, C&D concedes that these decisions remain the law These decisions require the dismissal of this action.

marketing its drug illegally under the FDCA, the *JHP* court concluded it presents "an issue that would require a more complex finding from the agency" and granted JHP's motion on primary jurisdiction grounds because to do otherwise "would be to arrogate the authority of the FDA to decide, at least in the first instance, the legality or illegality of marketing a particular substance." *Id*. at *9. Finally, on Par's theory that the JHP labeling omits key safety disclosures, the Court acknowledged that "the area of drug labeling was specifically singled out by the *POM Wonderful* Court as being one where the FDA takes a particularly active role" and preclusion may therefore apply but again declined to reach the issue because the substantive allegations were deficient.

C&D's cursory summary of *Catheter Connections, Inc. v. Ivera Med. Corp*., No. 2:14-CV-70-TC, 2014 WL 3536573, at *4 (D. Utah July 17, 2014) is equally disingenuous. There, the plaintiff asserted Lanham Act claims challenging four alleged misrepresentations about a competing medical device. The court summarized *Pom Wonderful* as "leav[ing] open the possibility that [plaintiff's] claims do not intersect with the FDA's regulatory expertise." *Id.* at *4. Relying on *Photomedex, Inc. v. Irwin*, 601 F.3d 919, 922 (9th Cir. 2010), the court precluded plaintiff's theory that defendant's medical device was not covered by a 510(k) clearance for an earlier version of the device. The theory that a new FDA clearance was required for a modified product is barred because, "if that decision was wrong, the next step lies with the FDA, which may enforce the section and require a new submission by [defendant]." The other theories were not barred because they "focus on the substance of Ivera's representations in the context of the medical device market and what drives buyers' purchasing decisions."

Importantly, even though both *JHP* and *Catheter Connections* distinguished *Pom Wonderful* to bar Lanham Act claims based on FDCA preclusion or primary jurisdiction, the facts supporting those outcomes were far weaker than they are here. The barred claims did not directly conflict with FDA action; in both cases, the claims were that there had been ***no*** FDA

action. Nonetheless, they were barred because they could require a Court to apply the FDCA or to predict what action the FDA might take. Here, the FDA has already acted to approve the challenged advertising, and C&D's claims directly conflict with that action.

II. In This Case, The "Differing Purposes" Of The Lanham Act And The FDCA Converge To Bar C&D's Claim.

C&D repeatedly insists that the "differing purposes" of the Lanham Act and the FDCA protect C&D's claim from preclusion.[4] While C&D may be advancing its competitive interests, and the FDA's process aims to protect consumers, both C&D's claim and the FDA process address ***the same issue***: whether SPD's marketing materials adequately avoid consumer confusion over a specific issue. FDA resolved that issue in the affirmative; C&D seeks to resolve it in the negative.

The essence of C&D's "differing purposes" argument is this: the package insert disclosures may be adequate to protect consumers, but they are not adequate to protect C&D because they cannot affect the buying decision. But this argument assumes, without basis, that buyers are influenced by the deception C&D alleges ***at all***. That is, if buyers are every bit as likely (or even more likely) to buy the Product if they understand that it estimates time since ovulation, it makes no difference whether they understand that at the time of purchase or later.[5] Critically, ***C&D made no effort whatsoever*** to show that the hypothesized deception would influence buyers' decision-making. Memorandum in Support of SPD's Motion to Exclude Hal Poret, p 24; Memorandum in Support of SPD's Motion to Exclude Bruce Isaacson, p. 24.

The law does not allow C&D to assume that the purported deception, even if it were shown to occur, has resulted in harm to C&D. Rather, C&D must show that buyers are more

[4] If this theory were credited, the entire doctrine of FDCA preclusion would be a dead letter: by definition, every Lanham Act claim will be furthering the purpose of protecting competitors.

[5] C&D's asserts that "[t]he evidence [it] will present at trial will show . . . consumer deception. C&D Opp. at p. 11. We have now seen this "evidence" and, as explained in SPD's accompanying *Daubert* motions, it shows no consumer deception of any kind.

likely to buy the competing product instead of its product ***by virtue of that deception*** in order to have a case at all.[6] *See Procter & Gamble Co. v. Ultreo, Inc.*, 574 F. Supp. 2d 339, 350 (S.D.N.Y. 2008). This failure of proof is fatal to C&D's case regardless of whether FDCA preclusion applies. Since C&D has not even tried to do that, and the only evidence in the record indicates women who know the truth are more likely to buy the Product, ***the fact that certain disclosures on this point are inside the box works in C&D's favor***.

In short, while it may be true in general that the Lanham Act and the FDCA have differing aims, that difference does not avoid the actual conflict here. In the one context where it could matter in theory, C&D's failure of proof disposes of that theoretical concern.

III. C&D's Claim Directly Conflicts With The FDA's Decisions.

A. The FDA Necessarily Found That The Marketing Limitations It Imposed Avoid The Confusion C&D Is Alleging.

C&D describes as "extreme" SPD's observation that the FDA determined that marketing limitations it imposed would avoid the risk of consumer confusion. C&D argues that the Clearance Letter contradicts any such conclusion. C&D Opp. at p. 6. This position is frivolous.

The Clearance Letter explicitly states it is imposing marketing limitations pursuant to section 513(i)(1)(E) of the FDCA. DTX 011 at 2615. That section provides that, in the course of the 510(k) clearance process, the FDA "may require a statement in labeling that provides appropriate information regarding a use of the device not identified in the proposed labeling" ***provided*** the FDA makes certain specified "determinations." 21 U.S.C.A. § 360c(i)(1)(E). These include determinations that there is a "reasonable likelihood" of a use not identified in the proposed labeling and that such use "could" cause harm. *Id*. The FDA must then "specify the limitations on the use of the device not included in the proposed labeling." Most importantly, the

[6] This addresses C&D's frivolous suggestion that SPD bears the burden of showing that the buying decision is NOT influenced. The mere fact that C&D's failure of proof on its case-in-chief is also relevant to FDCA preclusion does not relieve C&D of its burden.

FDA may clear the device only "***if the labeling for such device conforms to the [specified] limitations***." *Id*. (emphasis added).

This language and structure make clear that, if the FDA makes the risk determination, it ***must*** also determine that the identified risks are adequately addressed by the resulting labeling "limitations" in order to clear the product at all. Here, the unintended uses the FDA expressly identified in the Hold Letter are ***exactly the same*** uses forming the basis for C&D's claim. Dkt. 224 at pp. 5-6; DTX 001 at 2653-54.

The FDA was explicit that clearance was conditional upon compliance with its limitations: "Provided you are able to adequately respond to all items in this hold letter and adequately address all review questions pertaining to this submission, we are considering an SE with limitations decision for clearance of this submission." DTX 001 at 2654. The FDA subsequently reconfirmed that clearance was contingent on the adequacy of labeling changes: "We believe that, ***if all deficiencies are adequately addressed,*** an SE with limitations decision may adequately resolve new questions about this intended use . . . ."

C&D's contention that the Clearance Letter contradicts this reality is baseless. The language C&D cites – which follows the explicit invocation of section 513(i)(1)(E) – says that clearance "does not mean that FDA has made a determination that your device complies with ***other*** requirements of the Act or any Federal statutes and regulations administered by ***other*** Federal agencies." C&D Opp. at 6 (emphasis added). In other words, the FDA's section 513(i)(1)(E) determination that the identified risks have been "adequately addressed" is not a determination that ***other*** parts of the FDCA have been satisfied.[7]

[7] C&D contends that its allegations that SPD is violating FDA's restrictions is not an effort at private enforcement of the FDCA but rather an evidentiary use of "the FDA's scientific conclusion about what the Product can and cannot do as additional factual support for its Lanham Act claim." But the FDA never made any "scientific finding" favoring C&D. The FDA never suggested, let alone "found," that ovulation is not a legitimate reference point for the

B. C&D's Claim Directly Conflicts With The FDA's Approval Of The Challenged Advertising.

C&D says that it is not asking the Court to mandate that the conversion chart be placed on the outside of the box and, therefore, its claim does not conflict with the FDA mandate to place the chart only in the Product leaflet. This argument, too, is frivolous. C&D cannot use its evasiveness in articulating what elements of the advertising it contends convey the alleged false message to also evade the clear conflict with FDA approval of this advertising. Indeed, the relief its claims describe is so vague as to be impossible to comply with.

Moreover, the FDA's mandate regarding the conversion chart is just one of many requirements the FDA imposed. The collective impact of those constraints is that, ***no matter what changes C&D's claim demands,*** they would run afoul of the FDA's comprehensive review. The FDA has stated that ***any*** material change to the packaging requires submission of a new 510(k) application – and therefore FDA approval. Dkt. 224 at pp. 20-21; Johnson DT at ¶ 17. If C&D were successful in forcing changes, SPD would be in the position of defying the Court or defying the FDA.

C&D also disputes that the FDA mandated that the conversion chart be confined to the product insert. The most compelling evidence of such a mandate is the Clearance Letter itself. Under the heading "Box Labeling," it says "Performance of the Weeks Estimator should not be displayed on your box labeling." Under the heading "Product Insert," the FDA made clear what it meant by "performance." It says, "Weeks Estimator performance should only be presented as follows" and it sets out the chart ***plus*** three bullet points that include accuracy figures.

Finally, C&D predictably argues that, although the FDA has approved the current versions of the packaging and the video advertisement, earlier versions are "very different" and

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start of pregnancy. The only relevant FDA determinations are that there is a chance of confusion between two legitimate reference points ***and that the marketing limitations the agency proposed are adequate to address it.***

preclusion should not apply. C&D also asserts that the "other advertising" was not pre-approved by the FDA.[8] But ***C&D*** contends that the differences between versions of the challenged advertising are ***immaterial.*** According to C&D, all versions of the packaging and the video advertisement (indeed, all of the advertising) convey exactly the same false message. Opp. at p. 20. C&D should not be heard to argue that the packages are identical in the message they convey to consumers but then insist that they are "very different" for preclusion purposes.

In any case, the FDA considered C&D's challenge to the launch packaging, the discontinued commercial and the "other advertising" and ***declined to take the action C&D is now asking this Court to take***. DTX 028-031. Although the FDA had the power to do so, it did not order the cessation of sales of the launch package but required a single change to be phased in as the Product in the launch packaging was sold: replacement of the word "weeks" in the display windows with the words "weeks along" adjacent to the display windows. Similarly, because the FDA approved a video advertisement extremely similar to the discontinued commercial, a determination that the latter is misleading would conflict with the FDA approval of the internet video absent a showing that the differences *are* material. C&D has made no such showing.[9]

CONCLUSION

For the foregoing reasons, C&D's false advertising claims should be dismissed.

[8] C&D has not even nominally submitted evidence of consumer confusion with respect to the other advertising.

[9] It bears noting that, unlike a Lanham Act plaintiff, the FDA bears no burden of showing empirically that an element of an advertisement is likely to mislead consumers. If C&D is going to contend that the differences in the approved and "unapproved" versions of the advertising are material, it cannot rest on the fact that the FDA required certain changes but must supply ***evidence*** to suggest the differences affect consumer perception.

DATED: February 23, 2015 COBLENTZ PATCH DUFFY & BASS LLP

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